510(k) Summary
807.92(c)

JUN 2 4 2011

SPONSOR **807.92(a)(1)**

Company Name:	Diacoustic Medical Devices (Pty) Ltd
Company Address	19 Quantum Street Techno Park Stellenbosch, South Africa 7600
Telephone:	27 21 880 2033
Fax:	27 86 557 4391
Contact Person:	Matthys L. Cronje

Summary Preparation Date: March 2, 2011

DEVICE NAME **807.92(a)(2)**

Trade Name:	Sensi with Diagnostic Heart Murmur Software
Common/Usual Name:	Electronic Stethoscope/Heart Sounds Analyzer
Classification Name:	Electronic Stethoscope; Phonocardiograph
Regulation Number:	21 CFR 870.1875, 870.2390
Product Code:	DQD, DQC
Device Class:	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
Zargis Medical Corp	Zargis Acoustic Cardioscan	K083309
Meditron AS	Meditron II Thestethoscope System	K013725

DEVICE DESCRIPTION **807.92(a)(4)**

The Sensi with Diagnostic Heart Murmur Software is a decision support device intended to acquire, record, and analyze heart sounds. It is used to distinguish between normal/physiological and pathological heart murmurs by recording the acoustic signal of the heart and the ECG signal simultaneously and analyzing these signal.

The complete system is a CD comprising Sensi Diagnostic Heart Murmur Software that runs on a computer with Windows operating system, instructions for use, the WelchAllyn Master Elite Stethoscope and the WelchAllyn Meditron Analyzer that captures the acoustic heart and ECG signals.

The Sensi Diagnostic Heart Murmur Software distinguishes between normal/ physiological and pathological heart murmurs by analyzing the acoustic heart and ECG signals captured with the WelchAllyn Meditron Analyzer. The device will record the acoustic sound of the heart at the four main auscultation positions and a three lead ECG signal. The ECG signal is not intended for diagnostic use, only to synchronize with the

beginning of each heart cycle. The acoustic heart signal is analyzed to identify heart sounds that may be present, identified sounds include S1, S2 and suspected systolic murmurs.

DEVICE INDICATIONS FOR USE **807.92(a)(5)**

The Sensi device consisting of the Sensi Diagnostic Heart Murmur Software, the WelchAllyn Master Elite Stethoscope and WelchAllyn USB Analyzer is a decision support device intended to be used on a single patient to assist the medical examiner in analyzing cardiac sounds for the identification and classification of suspected murmurs. It is used to distinguish between normal/physiological and pathological heart murmurs by recording the acoustic signal of the heart and the ECG signal simultaneously and analyze these signals. The acoustic heart signal is analyzed to identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected systolic murmurs.

Sensi indicates whether or not a recorded heart sound contains a suspected heart murmur and the confidence with which the analysis was made The device must be used in a clinical setting by trained personnel with the prescribed accessories and all relevant patient information must be taken into consideration before a diagnosis is made.

The interpretations of heart sounds offered by the Sensi device are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

Sensi is not intended to be a diagnostic device. It does not supersede the judgment of the qualified medical personnel. The device is intended to aid the physician in the evaluation of heart sounds. The physicians responsible for reviewing and interpreting the results, along with the auscultatory findings and medical history, in making a referral decision.

COMPARISON OF TECHNICAL CHARACTERISTICS **807.92(a)(6)**

The Sensi software device features were directly compared with the FDA cleared Zargis Acoustic Cardioscan and Meditron Stethoscope Analyzer.

Synopsis of the comparison analysis:

- All three software systems uses equivalent computer platforms.
- Both Sensi and Meditron uses equivalent accessories (electronic stethoscope and USB Analyzer – ECG). The acoustic performance between the Littmann and WelchAllyn electronic stethoscopes are equivalent.
- Both Sensi and Cardioscan uses equivalent signal processing algorithms. Sensi uses the QRS peak information from the ECG to segment the heart beats. No additional issues are introduced using this standard processing method and makes the process only more safe and effective.
- Patient information and signal display handling are in all three cases equivalent.
- Sensi and Cardioscan's clinical performances are equivalent.

SAFETY and EFFECTIVENESS **807.92(b)**

A comprehensive list of verification and validation testing was performed in accordance to Diacoustic's Design Control procedures.

Software validation was performed for all aspects of the Sensi System and Software. The graphical user interface and usability were compared to the predicate devices.

Validation of the Sensi was performed to ensure that the Sensi system consistently fulfills its intended use and the needs of the user. A clinical software validation was performed to insure the performance of the software algorithm

Study Type	Results
Feasibility & Usability Study	Usability validation was performed within real life clinical settings by intended users. On average all users scored the usability of the Sensi Software more than 4 out of 5.
Comparative Study between the FDA approved Zargis system and the Sensi	Sensi achieves overall accuracy of 70.8% Cardioscan achieves an accuracy of 67.9%
Design verification of a CAA algorithm	Specificity of 94% and sensitivity of 91%
Comparison of the Sensi software program's graphical user interface and usability to that of three other comparable software programs	The graphical user Sensi compares favorably to the three auscultation analysis packages with similarities between all the major display and interface functions
Validate algorithms used to distinguish between functional and pathological heart murmurs in the pediatric population.	1568 heart sounds were accepted to meet the criteria of good quality and match the recorded pathological condition

CONCLUSION **807.92(b)(3)**

Based upon the indications for use, technological characteristics and safety and performance testing, it is the conclusion of Diacoustic Medical that the Sensi device consisting of the Sensi Diagnostic Heart Murmur Software, the WelchAllyn Master Elite Stethoscope and WelchAllyn USB Analyzer is as safe and effective as the predicate devices and raises no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 22 2011

Diacoustic Medical Devices (Pty) Ltd.
c/o Mr. E.J. Smith
Smith Associates
1468 Harwell Ave.
Crofton, MD 21114

Re: K110704
Trade Name: Sensi Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: June 6, 2011
Received: June 6, 2011

Dear Mr. Smith:

This letter corrects our substantially equivalent letter of June 24, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110704

Indications for Use

510(k) Number (if known): _____

Device Name: Sensi

Indications for Use:

The Sensi device consisting of the Sensi Diagnostic Heart Murmur Software, the WelchAllyn Master Elite Stethoscope and WelchAllyn USB Analyzer is a decision support device intended to be used on a single patient to assist the medical examiner in analyzing cardiac sounds for the identification and classification of suspected murmurs. It is used to distinguish between normal/physiological and pathological heart murmurs by recording the acoustic signal of the heart and the ECG signal simultaneously and analyze these signals. The acoustic heart signal is analyzed to identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected systolic murmurs.

Sensi indicates whether or not a recorded heart sound contains a suspected heart murmur and the confidence with which the analysis was made The device must be used in a clinical setting by trained personnel with the prescribed accessories and all relevant patient information must be taken into consideration before a diagnosis is made.

The interpretations of heart sounds offered by the Sensi device are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

Sensi is not intended to be a diagnostic device. It does not supersede the judgment of the qualified medical personnel. The device is intended to aid the physician in the evaluation of heart sounds. The physicians responsible for reviewing and interpreting the results, along with the auscultatory findings and medical history, in making a referral decision.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110704